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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,620	03/24/2004	Jessie L.-S. Au	TNI-2-011	4039

266 7590 07/16/2008

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,620	AU ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,26-28 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,26-28 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicant's request for a Pre-Brief Conference, filed 6/17/2008 has been received. In summary of the Pre-Brief Conference, the panel decided that in view of *In re Gulack*, the 35 U.S.C. 103 rejection of claims 22, 26-28, and 30-34 set forth in the Final Office Action mailed 12/12/2007 cannot be maintained.

However, the panel also determined that *In re Ngai*, which has a fact pattern more closely related to the present claims, would support the rejection of the presently claimed pharmaceutical kit over prior art which teaches a kit comprising suramin formulated in a pharmaceutical carrier and instructions. The *content* of such instructions (both in the prior art and in the instant claims) is not given patentable weight in view of *In re Ngai*.

Accordingly, prosecution is hereby reopened and the finality of the previous Office Action is ***withdrawn***.

Notice of Appeal

The Notice of Appeal filed 6/17/2008 is deemed **moot** in view of the withdrawal of the finality of the previous Office Action and reopening of prosecution.

Claim Objections

Claim 22 is objected to because of the following informalities: there is both a comma and a period after the word "patient" in line 12. Applicant inserted the comma in the claim amendments filed 9/10/2007 but did not delete the period. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 26-28, and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bayer Product Information Sheet for Suramin (2 pages, published July 1985) (newly cited).

The Bayer Product Information sheet for suramin teaches that suramin is provided in vials containing 1 g of suramin. A vial is reasonably a "pharmaceutical carrier" as recited in the instant claims. The Bayer Product Information sheet for suramin also provides instructions for preparing suramin solutions for injection, instructions for administration, and instructions for dosage.

Accordingly, the claims are deemed properly rejected as being anticipated by the Bayer Product Information Sheet for suramin, which teaches that suramin is provided in vials and provides instructions for its use as a pharmaceutical agent. In is noted that *In re Ngai* supports the rejection of pharmaceutical kits that differ from the prior art only in the content of the provided instructions. The following section of the M.P.E.P., as noted by Applicants in their response filed 9/10/2007 (page 7) is deemed relevant to the present claims:

> "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (Claim at issue was a kit requiring instructions and a buffer agent. The Federal Circuit held that the claim was anticipated by a prior art reference that taught a kit that included instructions and a buffer agent, even though the content of the instructions differed.). See also *In re Gulack*, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983) ("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability .... [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.")." M.P.E.P. § 2112.01

The decision in *Gulack* held that there must be a functional relationship between the printed matter and a substrate in order for printed material to have any patentable weight. However, in *Ngai*, the court distinguished claims directed to a kit comprising instructions and a buffer (more closely related to the present case) from the printed band and instructions at issue in *Gulack*. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. In *Ngai*, addition of a new set of instructions into a known kit was held to not interrelate with the kit in the same way as the numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its

educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. In the present case, the printed matter in no way depends on the kit (*i.e.*, a kit containing suramin formulated in a pharmaceutical carrier), and the kit does not depend on the printed matter (*i.e.*, instructions for administering suramin in combination with cytotoxic agents). All that the printed matter does is teach a new use for an existing product. As the court stated in *Ngai*, "If we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product. This was not envisioned by *Gulack*. Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product." (Emphasis added).

Applicant notes in his Pre-Brief Conference request that "even Ngai's ultimately issued patent contained a 'kit' claim". This is true. However, what Applicant fails to note is that Ngai amended the ultimately issued claim 19 after the decision in *In re Ngai*. Claim 19 in USP No. 6,982,143 reads:

> A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a **premeasured portions of** oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, Rnase H, DNA pol I, buffers and nucleotides (emphasis added).

Compare the claim language of claim 19 in USP No. 6,982,143 to the language of claim 19 under consideration in *In re Ngai*:

> A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a **premeasured portion of a reagent selected from the group consisting of**: oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, *buffers* and nucleotides (emphasis added).

The Examiner is hopeful that Applicant would agree that the scope of these two claims is drastically different and that the issued claim 19 could not be anticipated by prior art that teaches a kit comprising a 10X buffer and instructions as claim 19 at issue in *In re Ngai* was.

In view of the court decisions in *Gulack* and especially *Ngai*, it is the position of the Examiner that the instantly claimed instructions for using suramin in combination with cytotoxic

agents do not provide a functional relationship between the printed matter and a substrate and thus are not given patentable weight. All the printed matter does is teach a new use for an existing kit comprising suramin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 22, 26-28, and 30-34 under 35 U.S.C. 103 as being obvious over USP No. 6,855,338 to Dupont, is withdrawn in light of the Pre-Brief Conference held 7/10/2008. In summary, while Dupont teaches kits comprising suramin, he does not teach that such kits contain any instructions. Accordingly, the instructions recited in the present claims cannot be ignored (per *In re Gulack*) in the present obviousness rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 22, 26-28, and 30-34 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 11/193,883 is withdrawn in light of Applicant's cancellation of claim 29 from the '883 application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614